

## Residual DNA *E. coli* Kit

### *High sensitivity for optimal product safety*

The removal of host cell impurities is a critical step in the production of biopharmaceutical products. The Roche Residual DNA *E. coli* Kit is designed and validated for detection of residual *E. coli* DNA in biopharmaceutical products (protein solution, antibodies, etc.) as required by regulatory authorities.

Based on proven real-time qPCR technology, this kit makes detection of residual DNA from *E. coli* bacteria fast and reliable\*. It was developed to meet sensitivity requirements defined by WHO and FDA (10 ng *E. coli* DNA per therapeutic dose).

#### **Achieve high sensitivity and specificity through improved tests\***

- Linearity: 10 µg/ml to 5 pg/ml
- Lower Quantitation Limit: 5 pg/ml (50 fg/reaction)
- Lower Detection Limit: 1 pg/ml (10 fg/reaction)
- No cross-reactivity with unrelated DNA

#### **Rely on a robust test procedure for a wide range of sample types**

- Suitable for different matrices and a broad range of sample types from both in-process samples to bulk drug substances
- High lot-to-lot consistency of kit reagents, leading to reproducible results

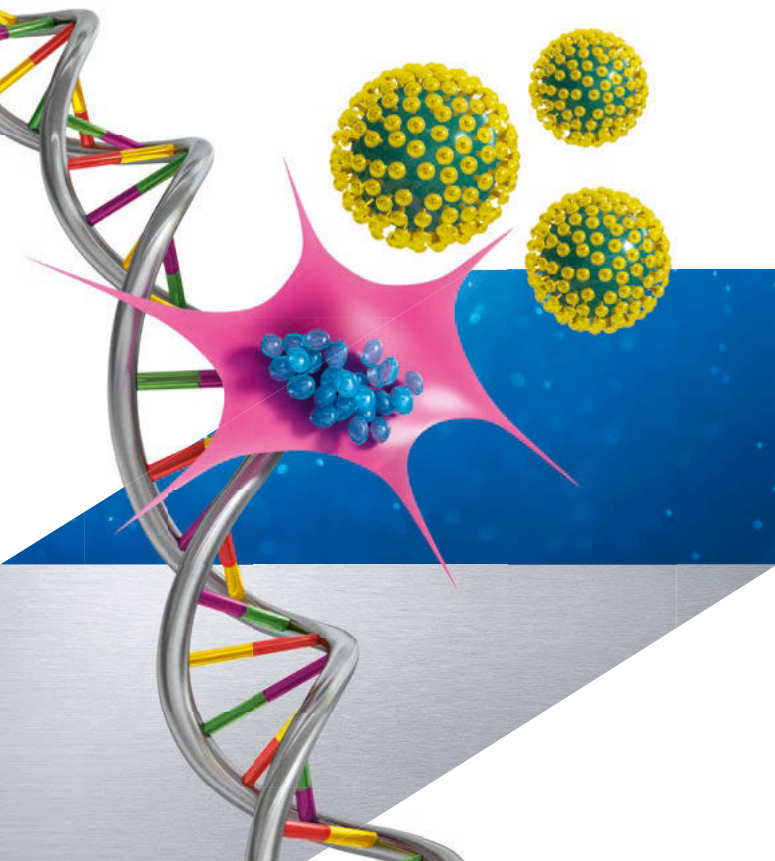
#### **Save time with proven real-time qPCR technology**

- Time to result <5 hours\*

#### **Characteristics**

##### **Residual DNA *E. coli* Kit**

<b>Sample prep</b>	Manual protocol optimized for excellent DNA recovery (min 80%).
<b>Control concept</b>	DNA stock solution for preparation of extraction controls and internal controls for PCR performance included in kit.
<b>All reagents included</b>	Supplied and ready-to-use reagents jump start your assay.
<b>High quality</b>	Roche is certified according to ISO 13485. Change notification available upon request.



\*Data on file.

For use in quality control/manufacturing process only.

## Ordering information

### Products

Residual DNA *E. coli* Kit

QC Sample Preparation Kit

### Catalog number

07 728 735 001

08 146 829 001

### Additional Quality Control or In-Process Manufacturing Kits

MycotoOL Mycoplasma Real-Time PCR Kit (160 PCR reactions)

06 495 605 001

### MycotoOL PCR Mycoplasma Detection Kit (Block PCR analysis via gel)

MycotoOL Mycoplasma Detection Prep Kit

05 184 592 001

MycotoOL Mycoplasma Detection Amplification Kit

05 184 240 001

Residual DNA CHO Kit

07 427 689 001

### Instrument

LightCycler® 480 Instrument II

05 015 278 001

The Residual DNA *E. coli* Kit can also be used with other real-time PCR platforms (e.g., QuantStudio™ 6 Flex PCR System from Applied Biosystems®).

### Regulatory disclaimer

For use in quality control/manufacturing process only. The LightCycler® 480 Instrument is for life science research only. Not for use in diagnostic procedures.

### Trademark

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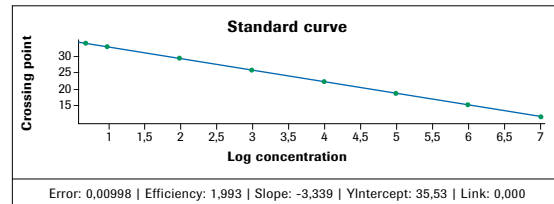
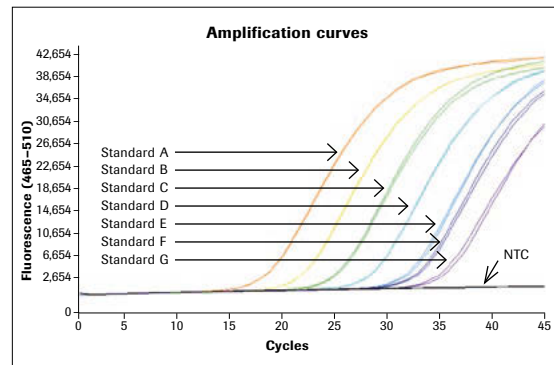
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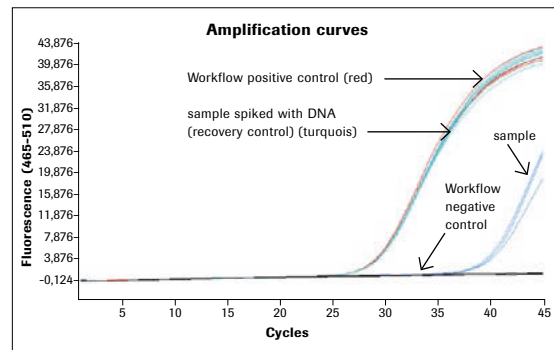
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**Figure 1:** Typical analysis results obtained with Standard A (100 000 pg/ml) to G (1 pg/ml). Standard curve is calculated to Standard F (5 pg/ml LOQ) and should be linear. PCR efficiency should be 1.85 or higher.



**Figure 2:** Typical results of a DNA spiked sample, a workflow positive and workflow negative controls. DNA recovery = minimum of 80% required.